Clinical Policy:Axitinib (Inlyta)

Reference Number: PA.CP.PHAR.100
Effective Date: 01/18
Last Review Date: 01/19

Coding Implications
Revision Log

Description
Axitinib (Inlyta®) is a kinase inhibitor.

FDA Approved Indication(s)
Inlyta is indicated for treatment of advanced renal cell carcinoma (RCC) after failure of one prior systemic therapy.

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria.

Policy/Criteria
It is the policy of health plans affiliated with Pennsylvania Health and Wellness that Inlyta is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Renal Cell Carcinoma (must meet all):

1. Diagnosis of RCC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. If clear cell histology, failure of one prior therapy *(Appendix B)* unless contraindicated or clinically significant adverse effects are experienced;
   **Prior authorization may be required.*
5. Request meets one of the following (a or b):
   a. Dose does not exceed 20 mg per day;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

B. Thyroid Carcinoma – Off-label Use (must meet all):

1. Diagnosis of differentiated thyroid carcinoma (DTC; i.e., follicular, Hurthle cell or papillary thyroid carcinoma);
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Disease is unresectable, locally advanced, or metastatic;
5. Failure of Lenvima® or Nexavar® unless contraindicated or clinically adverse effects are experienced;
   **Prior authorization may be required.*
6. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

Approval duration: 6 months

C. Other diagnoses/indications: Refer to PA.CP.PMN.53

II. Continued Approval

A. All Indications in Section I (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
2. Documentation of positive response to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):
   a. New dose does not exceed 10 mg twice daily;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use *(prescriber must submit supporting evidence)*.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to PA.CP.PMN.53

Background

Description/Mechanism of Action:
Axitinib is an oral agent that works by inhibiting receptor tyrosine kinases, including vascular endothelial growth factor receptors (VEGFR)-1, VEGFR-2, and VEGFR-3. These receptors are implicated in pathologic angiogenesis, tumor growth, and cancer progression.

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
DTC: differentiated thyroid carcinoma
FDA: Food and Drug Association
RCC: renal cell carcinoma

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Examples of RCC first and second-line therapies for relapse or stage IV disease per NCCN		

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
• Votrient® (pazopanib) • Sutent® (sunitinib) • Opdivo® (nivolumab) ± Yervoy® (ipilimumab) Avastin® (bevacizumab) ± (Intron A (interferon alfa-2b), Tarceva (erlotinib) or Afinitor®/Afinitor® Disperz (everolimus)) • Proleukin® (aldesleukin) • Cabometyx® (cabozantinib) • Torisel® (temsirolimus) • Inlyta® (axitinib) • Afinitor/Afinitor Disperz (everolimus) ± Lenvima (lenvatinib) • Nexavar (sorafenib) • Tarceva® (erlotinib)	Varies	Varies
DTC		
Lenvima (lenvatinib)	24 mg PO QD	24 mg/day
Nexavar (sorafenib)	400 mg PO QD	400 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings
None reported

IV. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
RCC	5 mg PO BID	20 mg/day

V. Product Availability

Tablets: 1 mg, 5 mg

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
N/A	

Reviews, Revisions, and Approvals	Date	Approval Date
Age, specialist and dosing added. Renal cell carcinoma: definition of "advanced" removed given the additional requirement of a prior systemic therapy. References reviewed updated.	02/18	
1Q 2019 annual review: thyroid carcinoma - DTC is added to diagnosis for clarity, metastatic/iodine refractory is removed and a drug trial is added per NCCN; references reviewed and updated.	01/19	

References

1. Inlyta Prescribing Information. New York, NY: Pfizer Labs, Inc.; August 2018. Available at http://labeling.pfizer.com/ShowLabeling.aspx?id=759. Accessed October 15, 2018.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at nccn.org. Accessed October 15, 2018.
3. National Comprehensive Cancer Network Guidelines. Kidney Cancer Version 1.2018. Available at nccn.org. Accessed October 15, 2018.
4. National Comprehensive Cancer Network Guidelines. Thyroid Carcinoma Version 1.2018. Available at nccn.org. Accessed October 15, 2018.
5. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2018. Available at: http://www.clinicalpharmacology-ip.com/.